Notice of Allowability

Application No.	Applicant(s)
09/686,346	Cobb et al.
Examiner	**Art Unit**
Maryam Monshipouri	1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.

2. ☒ The allowed claim(s) is/are *49-68*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____.
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   *Certified copies not received: _____.

5. ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

   (a) ☐ The translation of the foreign language provisional application has been received.

6. ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

8. ☒ CORRECTED DRAWINGS must be submitted.

   (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

   1) ☒ hereto or 2) ☐ to Paper No. _____.

   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the examiner.

   (c) ☐ including changes required by the attached Examiner's Amendment/Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1 ☐ Notice of References Cited (PTO-892)
2 ☐ Notice of Informal Patent Application (PTO-152)
3 ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
4 ☒ Interview Summary (PTO-413), Paper No. *16*.
5 ☒ Information Disclosure Statement(s) (PTO-1449), Paper No(s). *7*
6 ☒ Examiner's Amendment/Comment
7 ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
8 ☒ Examiner's Statement of Reasons for Allowance
9 ☐ Other

Mark Wilson 512 536 3000

#16/B

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Mr. Mark B. Wilson, on 5/23/2003 .

Examiner's Amendment to the Claims

Cancel claims 28-48.

Insert the following claims : ---

1 ~~49.~~ A method for screening for a modulator of *MAP* kinase signal transduction comprising:

(a) contacting a TAO2 polypeptide set forth as SEQ ID NO:4 or variant thereof having at least 80% homology to said TAO2 polypeptide and TAO kinase activity with an agent;

(b) incubating said contacted TAO2 or variant thereof with a MEK3 or MEK6 polypeptide; and

(c) determining the level of said MEK3 or MEK6 activation,

wherein detecting a change in the level of the MEK3 or MEK6 activation relative to the MEK3 or MEK6 incubated with said TAO2 polypeptide or said variant thereof not contacted with said agent indicates that said agent is a modulator.

2 ~~50.~~ A method for screening for a modulator of *MAP* kinase signal transduction comprising:

(a) contacting a cell expressing a TAO2 polypeptide set forth as SEQ ID NO:4 or a variant thereof having at least 80% homology to said TAO2 polypeptide and TAO kinase activity and a MEK3 or MEK6 polypeptide with an agent; and

(b) determining the level of said MEK3 or MEK6 activation,

wherein detecting a change in the level of the MEK3 or MEK6 activation in said contacted cell relative to a cell not contacted with said agent indicates that said agent is a modulator.

51. The method of claim 49 or 50, wherein said TAO2 variant is contacted with said MEK3 or MEK6 polypeptide.

52. The method of claim 51, wherein said TAO variant is selected from the group consisting of:

(a) amino acid residues 1-320 of TA02;

(b) amino acid residues 1-416 of TA02; and

(c) amino acid residues 15-285 of TA02.

53. The method of claim 49 or 50, wherein said modulator increases *MAP* kinase signal transduction.

54. The method of claim 49 or 50, wherein said modulator decreases *MAP* kinase signal transduction.

55. The method of claim 49 or 50, wherein said MEK3 or MEK6 activation is indicated by MEK3 or MEK6 phosphorylation.

56. The method of claim 55, wherein a decrease in the MEK3 or MEK6 phosphorylation indicates a decrease in *MAP* kinase signal transduction.

9 ~~57.~~ The method of claim 7, wherein an increase in the MEK3 or MEK6 phosphorylation indicates an increase in *MAP* kinase signal transduction.

10 ~~58.~~ The method of claim 1 or 2, wherein said agent is an antibody or antigen-binding fragment thereof.

11 ~~59.~~ The method of claim 10, wherein said antibody is a monoclonal antibody.

12 ~~60.~~ The method of claim 2, wherein said agent is an antisense polynucleotide or a ribozyme.

13 ~~61.~~ The method of claim 2, wherein said MEK3 or MEK6 activation is indicated by p38 activity.

14 ~~62.~~ The method of claim 13, wherein said p38 activity is indicated by p38 phosphorylation.

15 ~~63.~~ The method of claim 14, wherein a decrease in p38 phosphorylation indicates a decrease in *MAP* kinase signal transduction.

16 ~~64.~~ The method of claim 14, wherein an increase in p38 phosphorylation indicates an increase in *MAP* kinase signal transduction.

17 ~~65.~~ The method of claim 2, wherein said MEK3 or MEK6 activation is indicated by expression of a reporter gene under the control of a MEK3- or a MEK6-dependent promoter.

18 ~~66.~~ The method of claim 17, wherein said MEK3- or MEK6-dependent promoter is ATF2.

19 ~~67.~~ The method of claim 1 or 2, wherein said TAO2 polypeptide or said variant thereof is contacted with the MEK3 polypeptide.

20 ~~68.~~ The method of claim 1 or 2, wherein said TAO2 polypeptide or said variant thereof is contacted with the MEK6 polypeptide. ---.

The following is an **Examiner's Statement of Reasons for Allowance**:

Claims 49-68 are directed to a method of screening for a modulator of MAP kinase signal transduction pathway comprising contacting TAO2 polypeptide of specific amino acid sequence, and specially claimed variants thereof with an agent "in vitro" or "in vivo", comprising incubating said polypeptides with MEK3 or MEK6 polypeptides and comparing the level of MEK3 or MEK6 activation in the presence and absence of said agent, wherein a change in the level of said MEK3 or MEK6 activation indicates that said agent is a modulator, optionally wherein: the agent can be an antibody, antisense or a ribozyme, and (optionally) the activation of MEK3 or MEK6 is, either indicated through p38 phosphorylation or by expression of a reporter gene under the control of a MEK3- or NEK6-promoter , such as ATF2.

Claimed TAO2 polypeptides and said variants thereof are free of prior art. Further the prior art does not teach or suggest preparing such specifically claimed TAO polypeptides or variants thereof. Hence, said polypeptides are novel and non-obvious. Since said TAO2 polypeptides and said variants thereof are both novel an non-obvious, methods of their use as specially claimed are also novel and non-obvious.

Claims 49-68 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308-1083. The Examiner can normally be reached daily from 8:30 A.M. to 4:30 P.M.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

M. Monshipouri

MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER

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